



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2014-F-0452]

Novus International, Inc.; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Novus International, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of poly (2-vinylpyridine-co-styrene) as a nutrient protectant for methionine hydroxy analog in animal food for beef cattle, dairy cattle, and replacement dairy heifers. Additionally, the petition proposes that the food additive regulations be amended to provide for the safe use of ethyl cellulose as a binder for methionine hydroxy analog to be incorporated into animal food.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comment, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-F-0452 for "Food Additives Permitted in Feed and Drinking Water of Animals; 2-Vinylpyridine-Co-Styrene." Received comments will be placed in the docket and, except for those submitted as

"Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comment only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carissa Doody, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6283, carissa.doody@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2295) has been filed by Novus International, Inc., 20 Research Park Dr., Saint Charles, MO 63304. The petition proposes to amend part 573 (21 CFR part 573) Food Additives Permitted in Feed and Drinking Water of Animals to provide for the safe use of poly (2-vinylpyridine-co-styrene) as a nutrient protectant for methionine hydroxy analog in animal food for beef cattle, dairy cattle, and replacement dairy heifers, and to provide for the safe use of ethyl cellulose as a binder for methionine hydroxy analog to be incorporated into animal food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the Agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see ADDRESSES) for public review and comment. Interested persons may submit to the Division of Dockets Management (see DATES and ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If,

based on its review, the Agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the Agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.51(b).

Dated: November 2, 2016.

Tracey H. Forfa,

Deputy Director,

Center for Veterinary Medicine.

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